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JUL 10 1996

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,309,445, which issued January 5, 1982, was filed on June 25, 1996, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, REDUX™ (dexfenfluramine hydrochloride), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156 if the approval of REDUX™ (dexfenfluramine hydrochloride) is considered to be the first permitted commercial use of the product. It is noted that the application argues that, although a racemate of REDUX™, fenfluramine (PONDIMIN®), has been previously approved, the prior approval of PONDIMIN® should not disqualify the approval of REDUX™ from being considered the first permitted commercial use of dexfenfluramine hydrochloride. See particularly Attachment E to the application for patent term extension.

Inquiries regarding this communication should be directed to Karin Tyson at (703) 306-3159.

Hiram A. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315

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